

REMARKS

This Amendment is being submitted in response to the Office Action mailed on February 7, 2008, in connection with the above-identified application.

Reconsideration of the above-identified application in view of the following remarks is respectfully requested.

STATUS OF ACTION

Claims 1, 3-17, and 19-21 are currently pending in the present application and under consideration. Applicants would like to thank the Examiner for the removal of the previously made rejection of claims 1, 3-17, and 19-21 as being anticipated by Phillips (US Patent No. 6,489,346) under 35 U.S.C. 102(e). Applicants respectfully request reconsideration of the currently pending claims in view of the below provided remarks.

REJECTION UNDER 35 U.S.C. SECTION 103

Claims 1, 3-17, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips US Patent No. 6,489,346 (hereinafter "Phillips"). Applicants respectfully traverse this rejection.

The Office states that Phillips teaches a non-enteric coated solid pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent and a method for treating acid-related gastrointestinal disorders comprising administering to a patient the non-enteric coated solid pharmaceutical composition. The pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal. (See, page 4 of Office

Action). Moreover, according to the Office, Phillips teaches that mixtures of the buffering agents can be utilized. (See, page 4 of the Office Action citing Phillips, col. 13, lines 47-53). Phillips further provides that the non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or an enantiomer, isomer, derivative, free base or salts thereof. (See, page 4 of the Office Action citing Phillips, Abstract).

Although, the Office acknowledges that Phillips does not teach the instant ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer being about 1:20 to about 10:1, the Office suggests that the determination of suitable or effective ratios is within the level of one of ordinary skill in the art, obtained by routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Applicants respectfully disagree with the Office's conclusion.

Applicants believe that the specific combination and ratios described by the present invention would not have been obvious to one of ordinary skill in the art even in view of Phillips, and that this is not a case of routine optimization. In particular, Applicants note that the specification specifically provides "[i]t has been surprisingly and unexpectedly discovered that the combination of acid neutralizers is capable of increasing the pH to a greater extent and maintaining the pH at increased levels for a great timer period than either of the acid neutralizers alone." (See, page 5 of specification). In contrast, Phillips makes no reference to the specific combination or ratios provided within the specification of the present invention, nor does it discuss the desired effects and surprising results that have been discovered through using a combination of acid neutralizers being selected from water-soluble and water-insoluble acid neutralizers. Phillips, on the other hand, only states that "at least one buffering agent", preferably sodium bicarbonate, and many other weak and strong bases (and mixtures thereof)

maybe used. (See, Phillips col. 13, lines 47-50). Phillips then further provides a laundry list of potential buffering agents, but does not specifically indicate that a specific combination of water-soluble and water-insoluble acid neutralizers is desirable or that one of ordinary skill in the art would see desirable effects from a particular combination of buffering agents, such as that specifically provided for and claimed by the present invention. Moreover, Phillips fails to even suggest that the specific combination of water-insoluble and water-soluble acid neutralizers, let alone specific ratios, would be desirable but instead just states that a combination of buffers may be used. Phillips fails to appreciate or recognize that the specific combinations as claimed in the present invention provide surprising and unexpected results by increasing the pH to a greater extent and maintaining the pH at increased levels for a greater time period than either of the acid neutralizers alone. Therefore, the mere suggestion that Phillips anticipates by providing a laundry list of potential buffering agents that may be combined together is not accurate because Phillips fails to recognize the effective results obtained by the specific combinations of acid neutralizers claimed and disclosed by the present invention. The present invention discloses a combination that is more than a mere optimization, but instead provides specific combinations of water-soluble and in-soluble acid neutralizers that provide surprising and unexpected results.

In view of the above-provided remarks, Applicants believe the Office's rejection has been overcome and has now been rendered moot. Applicants respectfully request reconsideration and removal of the current rejections.

CONCLUSION

Reconsideration and withdrawal of rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions concerning the above, he is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

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